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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,294	12/27/2001	Toshiyuki Sakai	442P090	9019
	90 11/23/2004		EXAM	INER
Nields Lemack 176 E Main Stre	K & Dingman eet Suite 8		YU, MI	SOOK
Westboro, MA			ART UNIT	PAPER NUMBER
			1642	
			DATE MAILED: 11/23/2004	Ĺ

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	10/030,294	SAKAI ET AL.
Office Action Summary	Examiner	Art Unit
	MISOOK YU, Ph.D.	1642
The MAILING DATE of this communication Period for Reply	appears on the cover sheet w	ith the correspondence address
A SHORTENED STATUTORY PERIOD FOR RETHE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CF after SIX (6) MONTHS from the mailing date of this communication - If the period for reply specified above is less than thirty (30) days, at If NO period for reply is specified above, the maximum statutory period for reply within the set or extended period for reply will, by standard to reply received by the Office later than three months after the meanned patent term adjustment. See 37 CFR 1.704(b).	DN. FR 1.136(a). In no event, however, may a n. a reply within the statutory minimum of thir eriod will apply and will expire SIX (6) MON tatute, cause the application to be seen.	reply be timely filed ty (30) days will be considered timely. ITHS from the mailing date of this communication.
1) Responsive to communication(s) filed on $\underline{0}$	7 Sentember 2004	
	This action is non-final.	
3) Since this application is in condition for allo	owance except for formal matt	ers, prosecution as to the merits is
closed in accordance with the practice unde	er <i>Ex par</i> te <i>Quayle</i> , 1935 C.D	. 11, 453 O.G. 213.
Disposition of Claims		
4) Claim(s) 1-5 is/are pending in the application 4a) Of the above claim(s) is/are without 5) Claim(s) is/are allowed. 6) Claim(s) 1-5 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and	drawn from consideration.	
Application Papers		
9) The specification is objected to by the Exam	iner.	
10) The drawing(s) filed on is/are: a) a	accepted or b) objected to b	y the Examiner.
Applicant may not request that any objection to t Replacement drawing sheet(s) including the corr	the drawing(s) be held in abeyand	ce. See 37 CFR 1.85(a).
11) The oath or declaration is objected to by the	Examiner. Note the attached	Office Action or form PTO-152
Priority under 35 U.S.C. § 119		
12) △ Acknowledgment is made of a claim for forei a) △ All b) △ Some * c) △ None of: 1. △ Certified copies of the priority docume 2. △ Certified copies of the priority docume 3. △ Copies of the certified copies of the priority docume * See the attached detailed Office action for a li	ents have been received. ents have been received in Ap riority documents have been r eau (PCT Rule 17.2(a)).	plication No eceived in this National Stage
Attachment(s) Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date 3/12/02.	Paper No(s)/	mmary (PTO-413) Mail Date ormal Patent Application (PTO-152) ts A and B.

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DETAILED ACTION

Election/Restrictions

Applicant's election of group I in the reply filed on 9/7/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). All non-elected claims are cancelled. Claims 1-5 are pending and examined on merits.

Information Disclosure Statement

The information disclosure statement filed 03/12/2002 contains two WO documents, i.e. WO 99/50412, and WO 99/61610 that are in Japanese and German respectively. It is noted that both documents are cited in the ISR. The English translation of the entire texts have not been submitted, therefore both documents have been considered to the extent (abstract, sequence listings, and some drawings) that the Examiner could understand.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, and 2 recite "under a stringent condition" but it is clear what the metes and bounds are. All dependent claims are also rejected because the scope

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encompassed by the dependent claims includes the hybridizing molecules under the unclear conditions.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-5 are interpreted as drawn to as a gene, and genus of nucleic acids encoding p51 5'untranslated region, wherein said gene or genus is in a recombinant plasmid (claim 3), in a transformant (claim 4).

The applicable standard for the written description requirement can be found: MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Prove Inc., 63 USPQ2d 1609; Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC 2004).

First, the base claims 1 as currently construed reads on the entire p51 gene comprising SEQ ID NO:2 plus an native enhancer region controlling the transcription of said coding region because Darnell et al., (1990, Molecular Cell Biology, 2nd Edition,

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pages 344-345 only) teach that a gene also includes enhancer. However, the specification does not disclose any enhancer element of p51 gene.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim 2 is partial structure in form of mutations, and/or hybridization under an unclear hybridization condition. There is not even identification of any particular portion of the structure that must be conserved in order to have the recited function. Further, claim 2 does not say the identity of the function. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acid molecules, given that the specification has only

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described SEQ ID NO: 1 and 2 (note SEQ ID NO:2 is a slightly longer than SEQ ID NO:1, otherwise identical). Therefore, only isolated nucleic acid comprising SEQ ID NO:1 and 2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, and 5 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 2, and 5, as written, do not sufficiently distinguish over nucleic acids, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

⁽b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 2, 3, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Acc. No. AQ168656 (16 October, 1998).

The claims are broadly interpreted as drawn to a nucleic acid sequence with various degrees of sequence similarities to either SEQ ID NO:1, or 2 (claim 1) or to specific portion of SEQ ID NO:2 (claim 2), wherein the claimed nucleic acid has p51 promoter activity (claim 1), or an undefined activity of the specific portion of SEQ ID NO:2 (claim 2), wherein a recombinant plasmid (claim 3), a transformant (claim 4), a nucleic acid probe (claim 5) are claimed.

GenBank Acc. No. AQ168656 teach a nucleic acid with 90.6 % similarity from nucleotide #672 to 1171 of instant SEQ ID NO:2 (note Exhibit A), and also teaches that the clone is in plasmid vector pBeloAAC11, which is a BAC cone in E. Coli strain DH10B. Thus, the strain of E. coli is a transformant. Since both claims 1, and 2 do not specify how many nucleic acid could be deleted, substituted, or added in the base sequence in SEQ ID NO:1, or the specific portion of SEQ ID NO:2 (note for example the claim construction of claim 1 (2), or claim 2 (8)), the scope is broadly interpreted as all of base deleted, substituted, and/or added. Therefore, it is concluded that the nucleic acid sequence of GenBank Acc. No. AQ168656 meets the structural imitation of the claimed nucleic acid. As for whether the nucleic acid of the art has either p51 promoter activity or has the unspecified function of the specific portion of SEQ ID NO:2, the Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the nucleic acid of possess the same functional characteristics of the instantly claimed nucleic acid. In the absence of evidence to the contrary, the

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burden is on the applicant to prove that the claimed nucleic acid (especially in claim 1 (2), and (5)) is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). Furthermore, the preamble recitation of probe in claim 5 is merely suggestive of an intended use and is not given patentable weight for purposes of comparing the claim with the prior art. The claim reads on the nucleic acid *per se*.

Claims 1, 2, and 5 are rejected under 35 U.S.C. **102(b)** as being anticipated by Yang et al., (1998, Molecular Cell, vol. 2, pages 305-316).

The claims are broadly interpreted as drawn to a nucleic acid sequence with various degrees of sequence similarities to either SEQ ID NO:1, or 2 (claim 1) or to specific portion of SEQ ID NO:2 (claim 2), wherein the claimed nucleic acid has related p51 promoter activity (claim 1), or an undefined activity of the specific portion of SEQ ID NO:2 (claim 2), a nucleic acid probe (claim 5) are claimed.

Yang et al., at Fig. 2A teach a genomic structure of p63 gene encoding at least 6 different splicing variants. It appears that p51 gene is same as p63 gene because GenBank Acc. No. AF124528 (Jan. 04, 2001) teaches that the C-terminal end of instant SEQ ID NO:2, more specifically nucleotides #5462 to #5960 of SEQ ID NO:2 is exon 1 of p63 (note Exhibit B) shown in Fig. 2A of Yang et al., at page 314 under the heading "Cloning of p63" teaches a 120 kb clone that contains all of the human p63 gene, also teach at page 308, right column "the human p63 PAC clone as a probe" is

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used to map the gene to 3q27-29 (note also Fig. 3). Although Yang et al., do not list the nucleic acid sequence of the instant claimed promoter and/or 5' untranslated region sequence, it appears that the instantly claimed gene sequence and the sequence of p63 of the art are same. The court, especially Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989) stated that in order to be the same product, the art does not have to list the chemical composition of the product. Here, the human 120 kb clone used to map the p63 gene to 3q27-29 (note Fig. 3) appear to contain all of instantly claimed p51 gene including the promoter region, or the 5'-untranslated region. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the nucleic acid of possess the same functional characteristics of the instantly claimed nucleic acid. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed nucleic acid (especially in claim 1 (2), and (5)) is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). Furthermore, the preamble recitation of probe in claim 5 is merely suggestive of an intended use and is not given patentable weight for purposes of comparing the claim with the prior art. The claim reads on the nucleic acid per se.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-

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272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.

Examiner
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SUMMARIES

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ALIGNMENTS

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	COMMENT	PUBMED	MEDLINE	JOURNAL	TITLE			AUTHORS	REFERENCE			ORGANISM	SOURCE	KEYWORDS	VERSION	ACCESSION		DEFINITION	DEDITION OF	TOCILO	101 ARASA	RESIDE 1
High Throughput Sequencing Center University of Washington 401 Queen Anne Avenue North, Seattle, WA 98109, USA Tel: (206) 616-3618	Contact: Mahairas GG, Wallace JC, Hood L	10449764	99380589	Proc. Natl. Acad. Sci. U.S.A. 96 (17), 9739-9744 (1999)	Sequence-tagged connectors: A sequence approach to mapping and	Hood, L.	Keller, A., Shaker, R., Furlong, J., Young, J., Zhao, S., Adams, M.D. and	Mahairas, G.G., Wallace, J.C., Smith, K., Swartzell, S., Holzman, T.	1 (bases 1 to 523)	Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.	Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;	Homo sapiens	Homo sapiens (human)	GSS.	AQ168656.1 GI:3566331	AQ168656	<pre>saprens genomic crone riace=3165 Coi=16 Row=L, genomic survey sequence.</pre>	Has 3165 BZ FUR T/ CIT Approved Human Genomic Sperm Library D Homo	ACTOROGO SZS DP DNA Linear GSS 16-OCT-1998			

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COMMENT MEDLINE JOURNAL TITLE

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Nikaido, I., Osato, N., Saito, R., Suzuki, H., Yamanaka, I., Kiyosawa, H., Yagi, K., Tomaru, Y., Hasegawa, Y., Nogami, A., Schonbach, C., Gojobori, T., Baldarelli, R., Hill, D.P., Bult, C., Hume, D.A., Quackenbush, J., Schriml, L.M., Kanapin, A., Matsuda, H., Edhonbach, C., Corbani, L.E., Cousins, S., Dalla, E., Dragani, T.A., Chothia, C., Corbani, L.E., Cousins, S., Dalla, E., Dragani, T.A., Fletcher, C.F., Forrest, A., Frazer, K.S., Gaasterland, T., Gustinoldi, M., Gissi, C., Godzik, A., Gough, J., Grimmond, S., Gustinoldi, M., Gissi, C., Godzik, A., Gough, J., Grimmond, S., Gustinoldi, M., Kawasawa, Y., Kedzierski, R.M., King, B.L., Konagaya, A., Kurochkin, J. V., Lee, Y., Lenhard, B., Lyons, P.A., Maglott, D.R., Maltais, L., Marchionni, L., McKenzie, L., Miki, H., Nagashima, T., Numata, K., Okido, T., Pavan, W.J., Pertea, G., Pespole, G., Petrovsky, N., Pillai, R., Pontius, J.U., Qi, D., Ramachandran, S., Schneider, C., Semple, C.A., Setou, M., Shimada, K., Varayai, T., Reed, J.C., Reed, D.J., Reid, J., Ring, B.Z., Ringwald, M., Sultana, R., Takenaka, Y., Taylor, M.S., Teasdale, R.D., Tomite, M., Varardo, R., Wagner, L., Wahlestedt, C., Wang, Y., Watanabe, Y., Wells, C., Wang, Y., Watanabe, Y., Walls, C., Yang, I., Yuang, I., Yuan, Z., Zavolan, M., Zhu, Y., Zimmer, A., Carminci, P., Sakazume, N., Sato, K., Shiraki, T., Waki, K., Kawai, J., Aizawa, K., Itoh, M., Kagawa, I., Miyazaki, A., Sakai, K., Sasaki, D., Shibata, K., Shinagawa, A., Yasunishi, A., Yoshino, M., Waterston, R., Lander, E.S., Analysis of the mouse transcriptome head on fence of the control of the c
12466851
                                                                                                 Nature 420,
                                                                                                                                              Analysis of the mouse transcriptome of 60,770 full-length cDNAs
                                                          22354683
                                                                                                       563-573 (2002)
                                                                                                                                                                                     based on functional annotation
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Bmail: genome-res@gsc.riken.go.jp,
URL:http://genome.gsc.riken.go.jp/
Adachi,J., Aizawa,K., Akimura,T., Arakawa,T., Carninci,P.,
Pukuda,S., Hashizume,W., Hayashida,K., Hirozane,T., Hori,F.,
Imotani,K., Ishii,Y., Itoh,M., Kagawa,I., Kawai,J., Kojima,Y.,
Kondo,S., Konno,H., Koya,S., Miyazaki,A., Murata,M., Nakamura,M.,
Nomura,K., Numazaki,R., Ohno,M., Ohsato,N., Saito,R., Sakazume,N.,
Sano,H., Sasaki,D., Sato,K., Shibata,K., Shiraki,T., Tagami,M.,
Takeda,Y., Waki,K., Watahiki,A., Muramatsu,M. and Hayashizaki,Y. Laboratory for Genome Exploration Research Group, RIKEN Genomic Sciences Center(GSC), Yokohama Institute
The Institute of Physical and Chemical Research (RIKEN)
1-7-22 Suehiro-cho, Tsurumi-ku, Yokohama, Kanagawa 230-0045, Jag Contact: Yoshihide Hayashizaki 81-45-503-9216 81-45-503-9222 Yokohama, Kanagawa 230-0045, Japan

Computer-based methods for the mouse full-length cDNA encyclopedia: real-time sequence clustering for construction of a nonredundant cDNA library. Genome Res. 11 (2), 281-289 (2001) cDNA library was prepared and sequenced in Mouse Genome Encyclopedia Project of Genome Exploration Research Group in Riken Genomic Sciences Center and Genome Science Laboratory in RIKEN. Division of Experimental Animal Research in Riken contributed to Direct Submission

Computational Analysis of Full-Length Mouse cDNAs Compared with Human Genome Sequences Mamm. Genome 12, 673-677 (2001)

Normalization and subtraction of cap-trapper-selected cDNAs to prepare full-length cDNA libraries for rapid discovery of new genes. Genome Res. 10 (10), 1617-1630 (2000)

RIKEN integrated sequence analysis (RISA) system--384-format sequencing pipeline with 384 multicapillary sequencer. Genome Res. 10 (11), 1757-1771 (2000) prepare mouse tissues. visit our web site (http://genome.gsc.riken.go.jp) for Location/Qualifiers

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FEATURES

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organism="Mus musculus"/ db_xref="taxon:10090"

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4.	CTCT 5284	4989	-
44	TCT 5278	39 CGGGTCAGGCAAAGCTTCTAAGGGGATGTGAAAGGGATATCTCTTTTCTCT	Manage .
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O1	TAA 4878 AAAA 5266	4819 ACAATAATATTATTTCCAATTTTAATATCTTTAAGAAAATTACTATATTATATGTAA	
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Ji	AAA 4758	4699 CAAAACAGCAAAAACTGTAAGACATAAAGAATAGAGTGGAGCCGACTGAGAGATTAAAA	
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	AAT 4100 	4041 TATTTGCTAATAGCAGGGAAGAAAGCCAAACTCTTTAACTGCAATTAACAAATCTATAÁT	
	CTA 4000 CTG 51868	3981 GGCTGTGGTCACAGGAAATTGATTATTTTAATTTCAGAACCTTCTATTTAGGTCATCTA	

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RESULT 11
HSP63G01
LOCUS
DEFINITION
ACCESSION

HSP63G01 835 bp DNA linear PRI 04-JAN-2001 Homo sapiens P63 protein (P63) gene, exon 1. AF124528

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5948 TGATATTTGGA 5958	B 65
5888 TTGGACTTTCTGTGGACTTAAAGTGGTCTGTGGACATATTTTCTGAATGTCTTTTTTGGT 5947	\$ Q
5 8 28	dd VQ
5768 TGAGTITGAAIGTGACATAACTTCTCAAAACTTAATTGAAGTGCCTTGTGTATTATGA 5827	Qy .
5708 AATTITGAAACTICACGGIGIGCCACCCIACAGIACTGCCCTGACCCTIACAICCAGCGG 5767	р Q
5648 TGTGTATATTTATĀĪRAATIGTĪCTCCGTTCGTTGATATCĀAAGACĀGTTGĀAGGĀAATG 5707 	Qy db
5588 TAGCATTTGACCCTATTGCTTTTAGCCTCCCGGCTTTATATCTATATATA	B 8
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1 (bases 1 to 835)

Yang,A., Kaghad,M., Wang,Y., Gillett,E., Fleming,M.D., Dotsch,V., Andrews,N.C., Caput,D. and McKeon,F.
p63, a p53 homolog at 3q27-29, encodes multiple products with transactivating, death-inducing, and dominant-negative activities motorcy. (2) (3), 305-316 (1998)
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Hagiwara, K., McMenamin, M.G. and Harris, C.C.
Direct Submission
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RESULT 12

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Vieira, A.R. and Murray, J.C.
Sequencing of Candidate Gen
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GCCACCCTACAGTACTGCCCTGACCCTTACATCCAGCGGTGAGTTTGAATGTGACATAAC
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/db_xref="taxon:9606"
/chromosome="3"
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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           note="found in alternatively spliced variants TA alpha
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